



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Diamond Animal Health, Inc.
USDA Vet Biologics Establishment Number	213
Product Code	1091.20
True Name	Bovine Respiratory Syncytial Virus Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Diamond Animal Health, Inc. Titanium BRSV - Elanco Animal Health - Diamond Animal Health, Inc. Titanium BRSV - Elanco US, Inc. - Diamond Animal Health, Inc.
Date of Compilation Summary	August 16, 2021

**Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Bovine Respiratory Syncytial Virus (BRSV)
<b>Study Purpose</b>	To demonstrate effectiveness against disease caused by infectious Bovine Respiratory Syncytial Virus
<b>Product Administration</b>	1 dose to calves 6-8 months of age.
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	BRSV Strain 375
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	September 20, 1993

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate safety of product under typical use conditions
<b>Product Administration</b>	One dose
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	NA
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	July 13, 1998